

REMARKS

Applicants thank the Examiner for the telephone interview of November 4, 2004, in which the declarations under 37 C.F.R. § 1.131 were discussed, and in which the Examiner stated that the previously submitted declaration by Kai Wucherpennig could be supplemented by a new declaration by co-inventor Jack Strominger.

Claims 1-20, 103, and 114-147 are pending in the present application. Claims 1-20 have been withdrawn by the Examiner as being directed to a non-elected invention.

Applicants note with thanks that the Examiner has indicated that claims 131-147 are allowable.

Applicants note with appreciation the withdrawal of the rejections of record under 35 U.S.C. 112, first paragraph.

Applicants note with appreciation the withdrawal of the rejections of record under 35 U.S.C. § 112, second paragraph.

Applicants note with appreciation the acceptance of the sequence listing.

Applicants reserve the right to pursue any cancelled subject matter in a future application. Issues raised in the Office Action are addressed in the order they were raised by the Examiner.

35 U.S.C. § 102(a)

1. Claims 103, 114-123, 128 and 129 stand rejected under 35 USC § 102(a) as allegedly being anticipated by Scott et al. (J. Exp. Med. 183: 2087-2095 (May 1996)), of record, as evidenced by U.S. Patent 5,837,816 (Ciardelli et al.; the “‘816 Patent”), of record.

The Examiner maintained the rejection for the reasons of record.

Applicants maintain that Scott et al. do not teach each of the limitations of the claims as currently recited for the reasons of record. Scott only teaches engineering of a soluble murine MHC class II molecule, IA, wherein claim 103 requires a human MHC Class II molecule.

The Examiner states at page 3 of the Office Action that “Applicant’s declaration under 35 USC § 1.131 is defective and therefore is not effective as evidence of prior conception. A declaration under 35 USC § 1.131 must be signed by ALL inventors of a claimed invention and the instant declaration was not signed by named co-inventor Jack Strominger.”

The Examiner stated at the bottom of page 3 of the Office Action that this “rejection and all other rejections based upon the Scott reference can be overcome by the filing of a proper declaration under 35 USC § 1.131.”

Applicants previously submitted a Declaration under 35 U.S.C. § 1.131 by inventor Kai Wucherpennig antedating the Scott et al. reference. Applicants note for the record that point no. 5 of the Declaration by inventor Wucherpennig sets forth conception and reduction to practice of the claimed invention with co-inventor Strominger. Thus, the Declaration makes clear that work on the claimed invention was by both inventors. Nonetheless, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 by co-inventor Jack Strominger antedating the Scott et al. reference. Thus, the declarations are now signed by ALL inventors.

Finally, Applicants request clarification of the Examiner’s position regarding the evidentiary teachings of the ‘816 Patent as the Examiner has not addressed this patent in the rejection. Nonetheless, Applicants submit that the ‘816 Patent cannot serve to cure any deficiencies of Scott et al as the ‘816 Patent does not teach or suggest human MHC Class II molecules of any species as currently claimed.

Therefore, Scott et al. is not available as prior art under 35 USC § 102(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejections Under 35 USC § 103(a)

2. Claims 103, 123, and 124 stand rejected under 35 USC 103(a) as allegedly being obvious over Scott et al. in view of U.S. Patent No. 5,837,816.

The Examiner’s position and Applicants’ rebuttal regarding Scott et al. has been discussed *supra*, and of record. Further, Applicants’ position regarding the ‘816 Patent has been discussed *supra*. Applicants maintain that the claims were not anticipated by, nor obvious in

view of Scott et al. and the '816 Patent either alone, or in combination. Murine MHC and human HLA molecules were clearly not equivalents that could be easily interchanged, and consequently, one of ordinary skill in the art at the time the invention was filed would not have had a reasonable expectation of success when contemplating the invention as recited. The deficiencies of Scott et al. cannot be cured by the teachings of the '816 Patent.

The Examiner stated at the bottom of page 3 of the Office Action that this "rejection and all other rejections based upon the Scott reference can be overcome by the filing of a proper declaration under 35 USC § 1.131."

Applicants' position with respect to the declaration under 35 U.S.C. § 1.131 has been addressed *supra*.

Therefore, Scott et al. is not available as prior art under 35 USC § 102(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

3. Claims 103 and 130 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Scott et al. in view of US Patent No. 6,015,884 (the "'884 Patent"; Schneck et al.), of record.

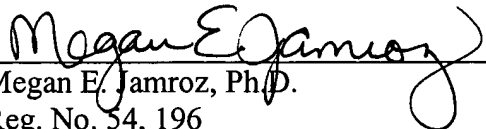
Applicant's position regarding Scott et al. and Schneck et al. has been described *supra*, and of record, and respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Respectfully Submitted,

Date: November 22, 2004


Megan E. Jamroz, Ph.D.
Reg. No. 54, 196
Ropes & Gray, LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Wucherpennig et al.

Serial No: 09/248,964

Filed: February 12, 1999

For: MONOVALENT, MULTIVALENT,
AND MULTIMERIC MHC
BINDING DOMAIN FUSION
PROTEINS AND CONJUGATES,
AND USES THEREFORE



Attorney Docket No. HUIP-P01-005

Art Unit: 1644

Examiner: F.P. Vandervegt

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. § 1.131 of Jack Strominger

Sir:

I, Jack Strominger, of Lexington, Massachusetts, hereby declare as follows:

1. I am a co-inventor of the above-mentioned application which teaches and claims monovalent, multivalent, and multimeric MHC binding domain fusion proteins and conjugates, and uses therefore.
2. I have reviewed the office actions dated July 29, 2003, and September 22, 2004, and understand that the Examiner has rejected the claims under 35 U.S.C. 102/103 in view of Scott et al., *J. Exp. Med.* 183: 2087-2095, published May 1996.
3. The invention as described and claimed in the above-identified application was conceived prior to the publication date of Scott et al. In support, we submit the Kalandadze et al. (*J. Biol. Chem.* 271(33): 20156-20162) publication as Appendix A.
4. The Kalandadze et al. publication describes work that is the subject matter of the instant claims. This work was carried out under my direction. I participated in and oversaw the drafting of the manuscript describing the results.
5. I point out that the manuscript was received by the journal for publication on March 18, 1996. I submit that no substantial revisions were made to the manuscript after that date. The

receipt date of the manuscript indicate both conception and reduction to practice of the claimed invention by myself and my co-inventor, Kai Wucherpennig, prior to May 1996.

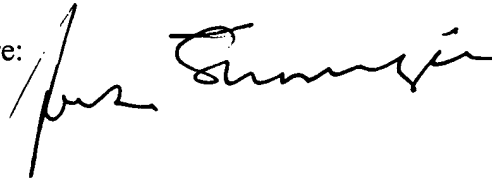
6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Jack Strominger

Dated:

11/10/04

Signature:

A handwritten signature in black ink, appearing to read "Jack Strominger", written over a horizontal line.